REMARKS

Favorable reconsideration is respectfully requested in light of the above amendments and the following comments. Claims 1 and 10 have been amended to more clearly define the invention. No new matter has been added, as these amendments are fully supported in the specification. For example, Figure 1 clearly shows a distal guidewire port 16 that is located at the distal end of the catheter and a proximal guidewire port 14 that is positioned proximal of the distal end of the catheter yet still within the distal portion of the catheter.

Applicant respectfully traverses the Examiner's rejection of claims 1-5 and 7 under 35 U.S.C. § 102(b) as anticipated by Moore et al., U.S. Patent No. 5,531,700 (hereinafter Moore). In order to anticipate, the cited reference must disclose each and every claimed element. Moore fails to do so.

In particular, claim 1 requires that the guidewire lumen extension be axially aligned with the guidewire lumen. Moore fails to disclose this feature. As illustrated, for example, in the Figures, axial alignment means that the guidewire lumen extension and the guidewire lumen share a common axis, i.e., they are aligned end to end such that a guidewire can pass through both the guidewire lumen and the guidewire lumen extension while remaining at least substantially straight. For example, Figures 3, 4A and 4B clearly demonstrate that the guidewire lumen extension is axially aligned with the guidewire lumen.

In contrast, Moore describes a guidewire lumen and a guidewire lumen extension that are arranged in parallel. Two parallel lumens neither describe nor suggest two lumens that are arranged in axial alignment, and thus for at least this reason, the rejection should be withdrawn. Favorable reconsideration is respectfully requested.

Applicant respectfully traverses the Examiner's rejection of claims 1-5 and 7 under 35 U.S.C. § 102(b) as anticipated by Salmon et al., U.S. Patent No. 5,314,408 (hereinafter Salmon). Salmon describes a catheter having a common distal lumen and several proximal lumens. A guidewire can be withdrawn from the common distal lumen so that an imaging or interventional device can be extended into and through the common distal lumen.

The claimed invention requires a guidewire lumen that extends between distal and proximal guidewire ports. The distal guidewire port is positioned at the distal end of the catheter shaft while the proximal guidewire port is positioned proximal of the distal end of the shaft but

still within the distal portion of the shaft. The claimed invention is directed to a single operator exchange or rapid exchange catheter in which the guidewire lumen is relatively short. This permits easy exchange of one catheter or other device for another without disturbing the guidewire or requiring an excessively long guidewire.

Salmon discloses a guidewire lumen that extends from a distal guidewire port positioned at or near the distal end of the catheter and a proximal guidewire port that appears to be positioned at or near the proximal end of the catheter (see, for example, Figure 12). Thus, Salmon fails to describe the claimed guidewire lumen.

With respect to Figure 9 (cited by the Examiner), no guidewire lumen extension appears to be shown, as there does not appear to be a guidewire port positioned therebetween. Instead, Figure 9 merely shows a common distal lumen opening into a pair of proximal lumens. Salmon fails to describe the claimed invention. Favorable reconsideration is respectfully requested.

Applicant respectfully traverses the Examiner's rejection of claims 1-5, 7 and 10-15 under 35 U.S.C. § 102(b) as anticipated by Crittenden et al., U.S. Patent No. 4,988,356 (hereinafter Crittenden). Crittenden describes a catheter having a guidewire lumen that extends through the catheter shaft. A slit provides intermediate access to the guidewire lumen. In particular, Crittenden is directed to a guide member that spreads the aforementioned slit and that can move along the slit in zipper-like fashion.

The Examiner appears to be looking at the guide member as allegedly disclosing the claimed invention. The guide member is not a catheter and thus cannot anticipate a catheter that has a guidewire lumen and a guidewire lumen extension that is positioned in axial alignment therewith. Favorable reconsideration is respectfully requested.

Applicant respectfully traverses the Examiner's rejection of claims 1-5 and 7-17 under 35 U.S.C. § 102(b) as anticipated by Willard et al., U.S. Patent No. 5,219,335 (hereinafter Willard). Willard describes an introducer catheter having a lumen that can be used to introduce a guidewire. This lumen terminates at a point proximal of the distal end of the catheter and communicates at said termination point with a second lumen that appears to extend the length of the catheter. These two lumens appear to be parallel and thus cannot be considered as axially aligned.

In view of the amendments and comments presented herein, favorable reconsideration in the form of a Notice of Allowance is respectfully requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By his Attorney,

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Marked Up Version to Illustrate Changes Made

In the Claims:

Claims 1 and 10 have been amended as indicated:

1. (Twice Amended) A single operator exchange biliary catheter for use in combination with a guidewire and an endoscope, comprising:

an elongate shaft having a proximal end, a distal end and an injection lumen extending therethrough;

a guidewire lumen extending through a distal portion of the shaft between a proximal guidewire port and a distal guidewire port, the guidewire lumen being in fluid communication with the injection lumen of the shaft, the proximal guidewire port disposed proximal of the distal end of the shaft within the distal portion [and distal of the proximal end] of the shaft, the distal guidewire port disposed at the distal end of the shaft;

a tubular member connected to the shaft, the tubular member extending proximally from the proximal guidewire port to a proximal end disposed distal of the proximal end of the shaft, the tubular member defining a guidewire lumen extension in fluid communication with the guidewire lumen and adapted to permit the guidewire to be retracted from guidewire lumen and re-inserted therein; and

wherein the guidewire lumen extension is axially aligned with the guidewire lumen.

10. (Twice Amended) A single operator exchange biliary balloon catheter for use in combination with a guidewire and an endoscope, comprising:

an elongate shaft having a proximal end, a distal end, an injection lumen and an inflation lumen extending therethrough;

an inflatable balloon disposed adjacent the distal end of the shaft in fluid communication with the inflation lumen;

a guidewire lumen extending through a distal portion of the shaft between a proximal guidewire port and a distal guidewire port, the guidewire lumen being in fluid communication with the injection lumen of the shaft, the proximal guidewire port disposed proximal of the distal end of the shaft within the distal portion [and distal of the proximal end] of the shaft, the distal guidewire port disposed at the distal end of the shaft; and

a tubular member disposed about the shaft, the tubular member having a proximal end disposed distal of the proximal end of the shaft, and a distal end disposed distal of the proximal guidewire port, the tubular member defining a guidewire lumen extension in fluid communication with the guidewire lumen and adapted to permit the guidewire to be retracted from guidewire lumen and re-inserted therein;

wherein the guidewire lumen extension is axially aligned with the guidewire lumen.